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Development of a video-microscopic method to compare the effect of a precipitation inhibitor

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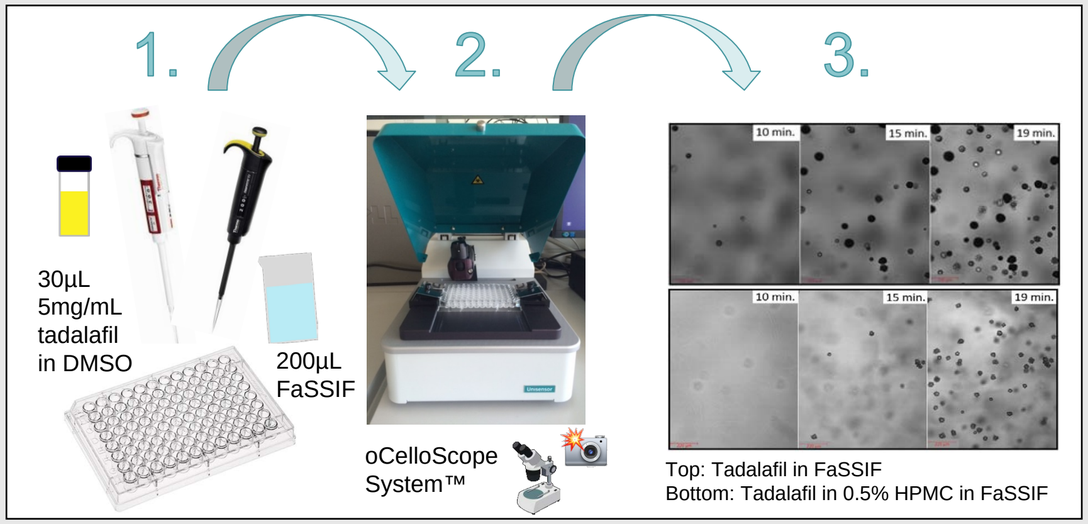
PURPOSE

The aim of this study was to develop a video-microscopic method to evaluate the effect of a precipitation inhibitor (PI) on supersaturated solutions of the poorly soluble drug tadalafil using a novel small scale setup.

CONCLUSION

- **Tadalafil shows a prolonged induction time and a reduced growth rate in presence of HPMC.**
- **To significantly prolong the induction time and decrease particle growth, 0.01 % w/v HPMC is needed.**
- **This is a promising tool for evaluating the effect of PI's on induction time and crystallization rate of supersaturated systems of poorly soluble drugs.**

METHOD



Top: Tadalafil in FaSSIF
Bottom: Tadalafil in 0.5% HPMC in FaSSIF

ACKNOWLEDGEMENTS

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UNIVERSITY OF COPENHAGEN

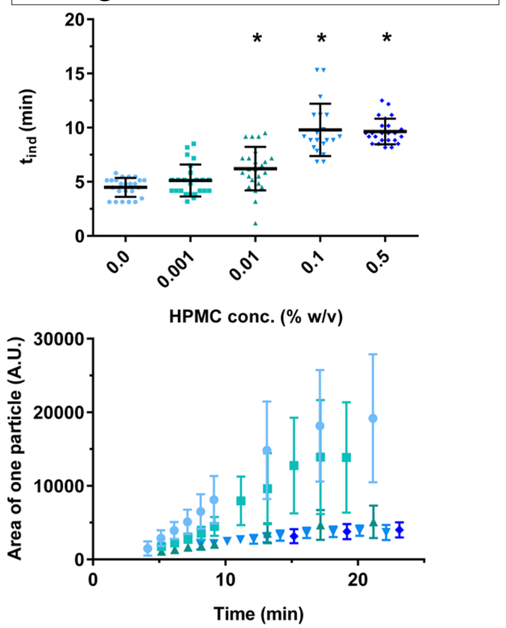
efpia

orbito
Innovative Tools for Oral Biopharmaceutics

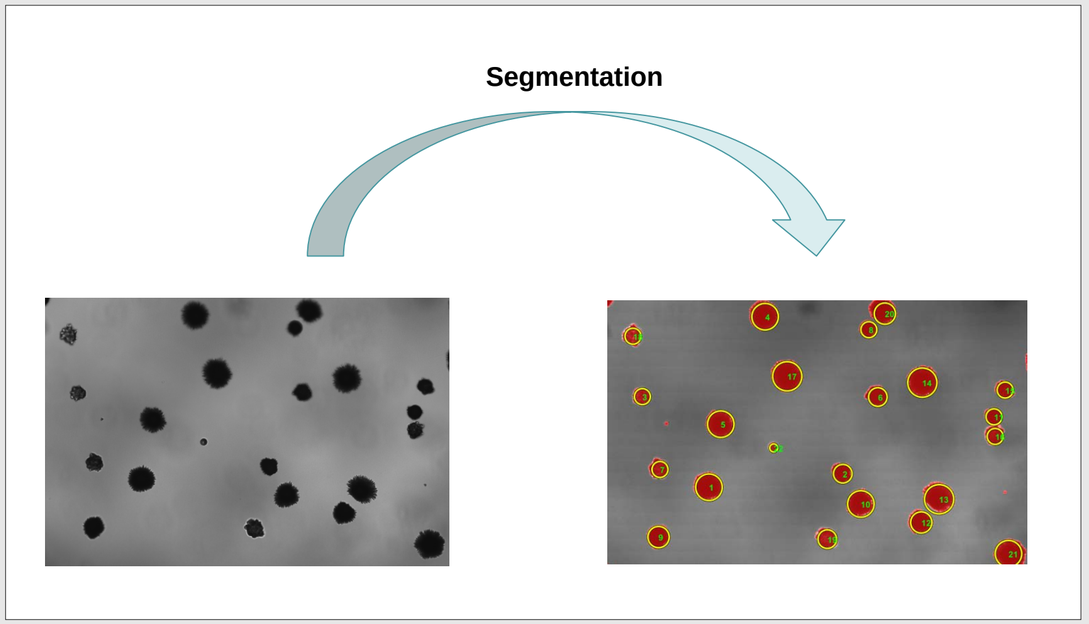
imi
Innovative Medicines Initiative

RESULTS

Proof of Concept using the commercial software

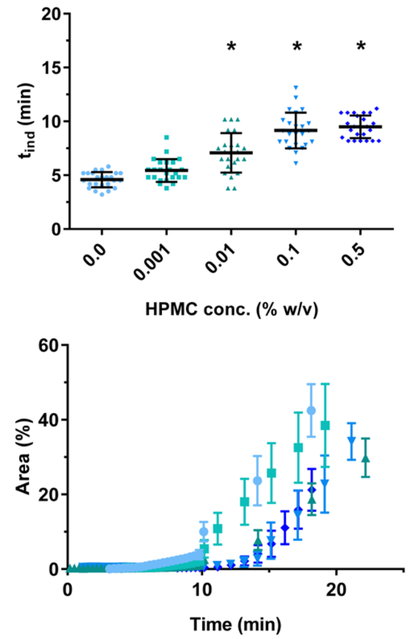


Top: Induction time for tadalafil in presence of HPMC
Bottom: The area of one well defined particle per well as a function of time, with different HPMC conc., mean ± SD, n=3-24



- 0.0 % (w/v) HPMC
- 0.001 % (w/v) HPMC
- 0.01 % (w/v) HPMC
- 0.1 % (w/v) HPMC
- 0.5 % (w/v) HPMC

Improved Image analysis



Top: Induction time for tadalafil in presence of HPMC
Bottom: The total particle area as a function of time, with different HPMC conc., mean ± SD, n=24